

REMARKS/ARGUMENTS

Present Invention and Pending Claims

Claims 1-8 and 15-17 are pending. Claims 1-8 are directed to a pharmaceutical composition. Claims 15-17 are directed to a method of treating a cardiovascular disorder.

Amendments to the Claims

Claim 15 has been amended to depend on claim 5. Claims 18-23 have been canceled without prejudice to reinstate. No new matter has been added by way of this amendment.

Summary of the Office Action

Claims 18-23 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description.

Claims 3-8, 16, 18 and 19 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 1, 7, and 8 have been rejected under 35 U.S.C. § 103(a), as allegedly obvious over Ault et al. (U.S. Patent Application Publication 2002/0123459) in view of Gumkowski et al. (U.S. Patent Application Publication 2003/0022944). Claims 2-5 have been rejected under 35 U.S.C. § 103(a), as allegedly obvious over Ault et al., in view of Gumkowski et al., and further in view of Cayman Chemical Company ("Cayman Currents," Summer 2002). Claims 15-23 have been rejected under 35 U.S.C. § 103(a), as allegedly obvious over Ault et al., in view of Gumkowski et al., and in view of Somers (U.S. Patent 6,147,250).

Claims 15-23 have been rejected on the grounds of obviousness-type double patenting over claims 1-6, 10, 11, 16-21, 34-40, and 53-58 of U.S. Patent 7,276,536 (Urata et al.) (hereinafter "the '536 patent") in view of Ault et al., Gumkowski et al., "Cayman Currents," and Somers.

Reconsideration of the pending claims is hereby requested.

Priority

According to the Office Action at page 2, the subject matter of claims 2-5 and 18-23 (claims 2-7 and 16-23 are indicated in the Office Action on page 3, items (i)-(iii)) is not supported by certain provisional applications to which the present application claims priority, namely, U.S. Provisional Patent Application 60/455,293, U.S. Provisional Patent Application 60/460,521, and U.S. Provisional Patent Application 60/477,202 (Office Action, paragraph bridging pages 2 and 3).

While Applicant does not agree with the Office's contention regarding the disclosures of U.S. Provisional Patent Application 60/455,293, U.S. Provisional Patent Application 60/460,521, and U.S. Provisional Patent Application 60/477,202, Applicant does not believe it is necessary to address these remarks by the Office at this time.

Discussion of the Written Description Rejection

Claims 18-23 allegedly lack written description. To advance prosecution and not in acquiescence of the rejection, claims 18-23 have been canceled. Therefore, the written description rejection has been rendered moot.

Discussion of the Indefiniteness Rejection

Claims 3-8 and 18 allegedly are indefinite.

Applicant could not determine the basis of the rejection of claims 3, 4, and 18 in the Office Action. The Office Action sets forth a discussion regarding the indefiniteness of only claims 5 (and claims 6-8, which are dependent on independent claim 5), 16, and 19. Applicant would appreciate clarification of the indefiniteness rejection of claims 3 and 4 (claim 18 has been canceled herein).

Regarding claim 5, the Office contends that the term "substantially" is a relative term which renders the claim indefinite. The term allegedly is "not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not reasonably be appraised of the scope of the invention" (Office Action, page 5, second paragraph).

Claim 5 is directed to a pharmaceutical composition comprising (i) *a substantially crystalline cholesteryl ester transfer protein (CETP) inhibitor, wherein the amount of inhibitor in amorphous form does not exceed about 10%*, and (ii) a water-insoluble concentration-enhancing additive, wherein the CETP inhibitor is JTT-705 (emphasis added). Applicant does not agree with the Office's contention that claim 5 does not define the term "substantially." JTT-705 can only be crystalline or amorphous. Since claim 5 states that "the amount of inhibitor in amorphous form does not exceed about 10%," the phrase "substantially crystalline" necessarily means that the amount of the inhibitor in crystalline form is about 90% or more. Therefore, claim 5 clearly defines the metes and bounds of the term "substantially."

The specification also provides a standard for ascertaining the degree of crystallinity (i.e., about 90% or more) required by claim 5. For example, paragraph 0078 of the specification states: "The amount of crystalline CETP inhibitor can be measured by powder X-ray diffraction, Scanning Electron Microscope (SEM) analysis, differential scanning calorimetry (DSC), or any other standard quantitative measurement."

Thus, claim 5 clearly establishes the metes and bounds of the term "substantially crystalline," and the specification clearly describes how to ascertain the requisite degree of crystallinity. As a result, one of ordinary skill in the art would reasonably understand the meaning and scope of this term, such that independent claim 5 (as well as claims 6-8, which are dependent thereon) is not indefinite.

Claim 16 allegedly is indefinite for reciting obesity as a cardiovascular disorder. Claim 16 recites that the cardiovascular disorder is selected from the group consisting of, *inter alia*, "hypertension, *and* vascular complications of diabetes, obesity or endotoxemia" (emphasis added). The last members of the Markush listing in claim 16 are vascular complications of diabetes, obesity or endotoxemia. In other words, the last members of the Markush listing are vascular complications of diabetes, vascular complications of obesity, and vascular complications of endotoxemia. Thus, claim 16 does not, in fact, recite that obesity is a cardiovascular disorder. Rather, claim 16 indicates that the cardiovascular disorder to be treated can be *vascular complications* of obesity. As a result, claim 16 is not indefinite.

Claim 19 allegedly is indefinite for reciting the phrase “or active form thereof.” As stated above, claim 19 has been canceled to advance prosecution and not in acquiescence of any rejection.

Based on the foregoing, Applicant respectfully requests the withdrawal of all of the indefiniteness rejections.

Discussion of the Obviousness Rejections

A. Ault et al. and Gumkowski et al.

Claims 1, 7, and 8 allegedly are obvious over Ault et al. in view of Gumkowski et al.

Applicant notes that claims 7 and 8 depend on claim 5 and not claim 1. Claim 5 is not subject to the obviousness rejection based on the combination of Ault et al. and Gumkowski et al.

Gumkowski et al. can be prior art to the present application only under 35 U.S.C. § 102(a) or (e). However, the accompanying Declaration under 37 C.F.R. § 1.131 establishes that the conception and reduction to practice of the present invention as defined by pending claims 1, 7, and 8 are *prior* to the earliest possible section 102(a) and 102(e) dates of Gumkowski et al. (i.e., prior to a section 102(a) date of January 30, 2003 and prior to a section 102(e) date of June 21, 2001). As such, Gumkowski et al. is not prior art to the present application under section 102(a), section 102(e), or any other subsection of section 102.

An obviousness rejection based on Ault et al. alone cannot stand. Ault et al. fails to teach each and every element of the claims, as implicitly conceded by the Office in relying on Gumkowski et al. to support the obviousness rejection. Independent claim 1 is directed to a pharmaceutical composition comprising (i) JTT-705 and (ii) crospovidone. Claims 7 and 8 require, *inter alia*, crystalline JTT-705 and a concentration-enhancing additive. As conceded by the Examiner, Ault et al. does not disclose JTT-705 and certainly not crystalline JTT-705. Ault et al. also does not disclose the use of any CETP inhibitors or even the treatment of cardiovascular disorders. Accordingly, Applicant respectfully requests the withdrawal of this obviousness rejection of claims 1, 7, and 8.

B. Ault et al., Gumkowski et al., and "Cayman Currents"

Claims 2-5 allegedly are obvious over Ault et al., in view of Gumkowski et al., and further in view of "Cayman Currents."

As discussed above with regard to the obviousness rejection of claims 1, 7, and 8, Gumkowski et al. is unavailable as prior art to the present invention as defined by the pending claims.

According to the Office Action, the reference referred to as "Cayman Currents" has a publication date of "Summer 2002" (Office Action, page 8, first full paragraph). Because no precise publication date is indicated, Applicant has assumed that "Summer 2002" implies a range of dates that in the northern hemisphere extend from the summer solstice (i.e., June 21, 2002) through the day before the fall equinox (i.e., September 22, 2002) of the publication year. However, "Cayman Currents" appears to be a publication that was disseminated by mail and, therefore, according to M.P.E.P. § 2128.02, is not considered to be prior art until it is *received* by at least one member of the public. See also *Carella v. Starlight Archery Pro Line Co.*, 804 F.2d 135, 231 U.S.P.Q. 644 (Fed. Cir. 1986) (for information to be considered a printed publication, sufficient proof must be provided of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents). Applicant was unable to find any date received stamp on the nearly illegible copy of "Cayman Currents" made available by the Office. Thus, there is no evidence that, even if "Cayman Currents" was published in "Summer 2002," the reference was disseminated to the public in the same period of time. Therefore, based on M.P.E.P. § 2128.02 and the applicable case law, it does not appear that the Office has properly established that "Cayman Currents," allegedly published in "Summer 2002," is indeed prior art to the pending application since no date has been set forth indicating when the reference became publicly available.

As discussed above, the only possible publication date currently established by the Office for "Cayman Currents" is a range of dates: "Summer 2002," which is understood to mean from June 21, 2002 through September 22, 2002. Since it is the Office's burden to determine the issue or publication date of a reference so that a proper comparison between the application and reference dates can be made (M.P.E.P. § 706.02(a)), Applicant has

presumed that the publication date is the last date of the date range equivalent to “Summer 2002.” Thus, “Cayman Currents” has been treated as having a publication date of September 22, 2002 (although “Cayman Currents” may well have even a later publication date, or even no publication date).

Even if, assuming for argument’s sake, that “Cayman Currents” was publicly available by September 22, 2002 (which the Office has failed to establish), “Cayman Currents” is not prior art to the present application.

In view of the foregoing analysis, “Cayman Currents” can be prior art, if at all, to the present application only under 35 U.S.C. § 102(a). However, the accompanying Declaration under 37 C.F.R. § 1.131 establishes that the conception and reduction to practice of the present invention as defined by pending claims 2-5 are *prior* to September 22, 2002. As such, “Cayman Currents” is not prior art to the present application under section 102(a) or any other subsection of section 102 based upon the information provided by the Office.

An obviousness rejection based on Ault et al. alone cannot stand. Ault et al. fails to teach each and every element of the claims, as implicitly conceded by the Office in relying on Gumkowski et al. and “Cayman Currents” to support the obviousness rejection. Accordingly, Applicant respectfully requests the withdrawal of this obviousness rejection of claims 2-5.

C. Ault et al., Gumkowski et al., and Somers

Claims 15-23 allegedly are obvious over Ault et al. in view of Gumkowski et al., and in view of Somers. Since claims 18-23 have been canceled, the following discussion pertains to claims 15-17.

Claim 15 and, therefore, claims 16 and 17, which are dependent thereon, have been amended to depend on claim 5, thereby requiring JTT-705 to be substantially crystalline. Gumkowski et al. does not disclose the crystalline form of any CETP inhibitor, let alone JTT-705. Instead, Gumkowski et al. describes the opposite by stating that the self-emulsifying formulations contain “no visibly detectable crystallization of CETP inhibitor” (paragraphs 0036, 0037, and 1060).

Ault et al. and Somers fail to cure the deficiencies of Gumkowski et al. In particular, neither Ault et al. nor Somers discloses JTT-705, let alone substantially crystalline JTT-705. Thus, the combination of Ault et al., Gumkowski et al., and Somers fails to result in a disclosure of each and every element of amended claims 15-17.

Without a disclosure or suggestion of each of the elements of claims 15-17, as amended, this obviousness rejection is without merit and should be withdrawn.

Discussion of the Obviousness-type Double Patenting Rejection

Claims 15-23 are rejected for obviousness-type double patenting over certain claims of the '536 patent in view of Ault et al., Gumkowski et al., "Cayman Currents," and Somers.

Insofar that claims 18-23 have been canceled, the following discussion pertains to claims 15-17.

Firstly, the Office fails to set forth a proper *prima facie* case of obviousness-type double patenting for the following reasons.

The Office has failed to establish the scope of claims 15-17 and has failed to make a comparison between the elements of claims 15-17 and the claims of the '536 patent. In particular, the similarities and differences between pending claims 15-17 and the cited claims of the '536 patent are not set forth in the Office Action.

The Office further fails to set forth a credible reason as to why one of ordinary skill in the art would turn to Ault et al. after considering the claims of the '536 patent. As noted by the Office, the claims of the '536 patent are directed to increasing the bioavailability of JTT-705. Ault et al. also is directed to a means of increasing the bioavailability of an active agent (e.g., calcitonin). The Office provides no credible reason for one of ordinary skill in the art to consider the disclosure of Ault et al. for an *additional* method of increasing the bioavailability of JTT-705 when the claims of the '536 patent already recite a solution to such a problem.

Secondly, as noted above, claims 15-17 have been amended to depend on claim 5, such that claims 15-17 now require that JTT-705 is substantially crystalline. Gumkowski et al. does not disclose the crystalline form of any CETP inhibitor, let alone JTT-705. Instead,

Gumkowski et al. describes the opposite by stating that the self-emulsifying formulations contain “no visibly detectable crystallization of CETP inhibitor” (paragraphs 0036, 0037, and 1060). Moreover, neither Ault et al. nor Somers discloses JTT-705, let alone substantially crystalline JTT-705.


Thirdly, for the same reasons discussed above in the context of one of the obviousness rejections, the Office has failed to establish that “Cayman Currents” is prior art to the pending application because no date has been set forth indicating when the alleged reference became publicly available. Accordingly, the burden to overcome “Cayman Currents” has not been shifted to Applicant.

Under these circumstances, it is clear that the Office has failed to set forth a proper *prima facie* case of obviousness-type double patenting. Accordingly, Applicant respectfully requests the withdrawal of the obviousness-type double patenting rejection of claims 15-17, as amended.

Conclusion

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

Respectfully submitted,



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